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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,115	06/23/2005	Ola Karlsson	1103326-0781	8848

7470 7590 11/14/2005

WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

WU, IVES J

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,115	KARLSSON ET AL.	
	Examiner	Art Unit	
	Ives Wu	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) 17-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All - b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/29/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 17-22 are cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Karlsson et al (WO 03087180A3).

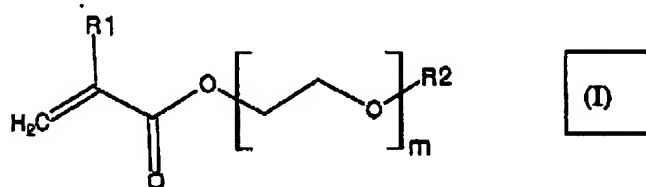
It is noted that the filing date (June 23, 2005) of this application 10/511,115 is beyond 18 months period after the filing date (April 09, 2003) of a national stage under PCT after compliance with 35 U.S.C. 371, and beyond 30 months period after the claimed priority for the filing date (April 12, 2002) of Foreign Applications: 0201110-4 Sweden. Accordingly, the reference of Karlsson et al (WO 03087180A3) is available as a prior art. See MPEP Section 1893.

Karlsson et al (WO 03087180A3) disclose a novel film coating dispersion obtainable by the polymerization of the following monomers in water: acrylic acid or an ester thereof in the range 40 to 80 wt%; methacrylic acid or an ester thereof in the range 20 to 60 wt%; and a polymerizable surfactant in the range 0.01 to 9 wt%. If the emulsifying agent is an emulsifier with a molecular weight lower than 15 kD then it is partially or fully removed after the

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polymerization reaction (page 10, line 4-5). The dispersion is suitable for coating pharmaceutical formulations to provide controlled release of the active ingredient (Abstract). Above and in the following the percentages refer to the percentage amount by weight of each monomer in the sum of the monomer weights. The sum of the percentages of each monomer is such that the total weight is always 100% (page 6, line 19-21).

A preferred polymerizable surfactant is a monomer characterized by formula I:



wherein m is an integer from 1-55,

R_1 is hydrogen or methyl, and

R_2 is hydrogen or a carbon chain having 1 to 20 carbon atoms.

(Page 7, line 15-24)

In another aspect of the invention provides an aqueous coating dispersion for use in coating pharmaceutical formulations obtainable by removal of water from one of the aqueous dispersions (page 11, line 5-7). In another aspect the invention provides an aqueous film coating dispersion for use in coating pharmaceutical formulations to provide controlled release (page 11, line 9-10). In another aspect, the invention provides a film coat covering a pharmaceutical core wherein the core comprises a pharmacologically active ingredient (page 12, line 1-2). In one embodiment, the active ingredient is a beta-blocking adrenergic agent such as metoprolol or a pharmaceutically acceptable salt thereof. The metoprolol salt can be a tartrate, succinate, fumarate or benzoate salt (page 12, line 23-26). The pharmacologically active ingredient is preferably an ingredient that has activity in the treatment of cardiovascular or gastrointestinal diseases (page 14, line 4-5). The invention also includes a process for the preparation of a film

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coating composition as described which comprises polymerizing the dispersions containing ethyl acrylate, methyl methacrylate, and the monomer described above in the range of 1 to 100 °C with an initiator as known in the art (page 15, line 1-4). The film coating can be used to coat a pharmaceutical core which includes one or more pharmacologically active ingredients, and optionally one or more pharmaceutically acceptable additives or excipients. The pharmaceutical active ingredient can be provided in a plurality of beads and coated with a film coat as defined above (page 17, 12-16).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ives Wu whose telephone number is 571-272-4245. The examiner can normally be reached on 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Examiner: Ives Wu
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Date: November 7, 2005



DAVID W. WU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700